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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/030,692

01/14/2002

Hans Rudolf Muller

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04/25/2005

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EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/030,692	Applicant(s) MULLER ET AL.	
	Examiner Mark L. Berch	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 29-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 29-37 and 43-46 is/are rejected.
- 7) ☒ Claim(s) 38-42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

AD

Art Unit: 1624

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/14/05 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13, 17, 32-34, 43-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. A hydrocarbon that "contains" e.g. oxygen is not correct. As stated in *In re Zletz*, 13 USPQ2d 1320, 1322, "An essential purpose of patent examination is to fashion claims that are precise, clear, correct and unambiguous." This term is not correct. The reasons for this were given previously, and the traverse is unpersuasive. Indeed, the current cls does not really make sense, since the first choice is the hydrocarbon radical, which applicants say does not have to be a hydrocarbon, so why is there the second choice at all? At any rate, the previous solution, which was to call it a hydrocarbon radical in one or more carbons replaced by heteroatoms actually solved that problem, except for the replacement with N itself. Applicants had stated that that this meant NH. Use of the

Art Unit: 1624

previous claim language, but with NH in place of N, would have completely solved the problem, and would have expressed what applicants state they meant. Given that the replacement with O, S or NH was what applicants say they intend, and would have completely resolved the matter, it is not clear why this was not done.

2. The use of "comprising" is improper for Markush groups (as in e.g. claim 1, choice ii). See MPEP 2173.05(h). This matter can be fixed by replacing "comprising" with "which is".
3. In claim 17, what is a "bridging group"? This term says where it is, but not what it is. The traverse is unpersuasive. There is no guidance as to what the nature of the bridge is, only where it is. The group is not being defined in terms of "what it does", but purely where it is. Applicants have cited *Amgen* in terms of the "insolubly ambiguous". First, the case did not say that any term which does not meet such a standard is definite. It said "Rather, a claim is indefinite under §112 ¶ 2 if it is "insolubly ambiguous...." But did not say that any term not meeting that standard is definite. Applicants have cited *Hallman*, but that case did not have an indefiniteness rejection. The examiner is not saying that there is anything intrinsically wrong with defining something in terms of what it does, but rather that there is no clear guidance as to what this bridge consists of. It does not itself do something. It is the entire molecule that does something. It simply is. The same is true for *Swinehart*, which simply held that the function of being transparent was sufficiently clear. Applicants state that the nature is "readily understandable", without stating what that understanding is. Instead, applicants point to the page 30, lines 19-29 material. If that is what is intended, insertion of this material will resolve the matter (thus, claim 44 is fine). But this language is much

Art Unit: 1624

different from the open-ended description in the remarks. For example, it is limited to no more than about 41 carbon atoms, (which would eliminate for example, many peptides, and most biologics), it doesn't include metals, etc. The claim language does not convey this.

4. "Heteroalkyl" is indefinite; there is no such thing. Is it a alkyl substituted by a heterocycle, e.g. pyridyl-methyl? An alkyl interrupted by a heteroatom, such as methoxymethyl? An alkyl substituted by a heteroatom, e.g. chloromethyl? Whatever choice is selected must be supported by the specification. Page 13 is noted, but these are just examples. It is impossible to tell the full scope of this. Can all the carbons be replaced with heteroatoms, and which heteroatoms can these be? Can the atom of attachment be the heteroatoms, e.g. can it be methoxy or NH_2 ? In addition, the carbon count is unclear. Is this the count before or the count after the substitution? Thus, would hydroxyalkyl be included? It started with two carbons, but after the substitution, it had one.
5. "Cycloaliphatic" makes no sense. Aliphatic means lacking in rings. The "cyclo" negates that, so what does the term mean?
6. The interruptions in the claim 46 definition for R100 are unclear. If it is an organic radical, it could already have these things present. Organic already provides for them.

Claims 1-2, 4, 8-19, 29-32, 34-37, 43-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of a "compound", which replaces the earlier "derivatives", is unclear. What qualifies as a compound and what does not? If the 4-oxo were instead thioxo, or =NR or

Art Unit: 1624

dihydrogen, or dimethyl, or removed, etc, would that still qualify? If the 2-amino group were dimethylamino, or nitro, or halo, or were removed, would that be a derivative? If an additional ring were fused onto the core (e.g. at the 6,7 positions or cyclized via the 2-amino group and some other position), or one or the other ring were opened up, would that be a pterin compound or would it not be? Would a metal complex of pterin qualify? Could any substituent at all appear at the 3-position? The traverse is unpersuasive. Applicants point out that "Numerous synthetics and naturally occurring pterin and pterin derivatives exist." The problem is not the existence of such compounds, it is the unknown line between compounds that fall within the claim and those which do not. The issue here is not whether or not the claim "may be broad", as the examiner has not raised the issue of breadth. It is not clear whether the new term "compound" is supposed to be broader, narrower or of the same scope as "derivative". The question here is not one of "inoperative embodiments" --- this is a rejection under paragraph 2. The examiner has also not asked for any "listing" of "all known pterin compounds". Applicants says "all pterin compounds are intended to be encompassed". The examiner understands that, but the scope of "pterin compounds" is not clear. Is a compounds which begins with the the structure given, but has additions rings fused (e.g. at the 6,7 positions or cyclized via the 2-amino group and some other position) in the category of pterins or not? It is by no means clear. Without a boundary between what is encompassed by the claim and what is not, the claim is indefinite.

Claim Objections

Claims 38-42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1624

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at 571-272-0661. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571)272-0674. The fax phone numbers for the

Art Unit: 1624

organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mark L. Berch
Primary Examiner
Art Unit 1624



April 21, 2005